Applicant T. St. Goar et al.

Serial No.: 10/635,776

Attorney's Docket No.: 17315-002001

Response to Office Action

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REMARKS

Claims 1, 8, 10, 11, 12, 14-18, 43 and 51-61 are pending in this application.

Reconsideration and allowance of the above-referenced application are respectfully requested.

Rejection of Claims 1, 8-10, 12, and 14-18 under 35 U.S.C. §102

Claims 1, 8-10, 12, and 14-18 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Number 6,269,819 to Oz. However, Oz fails to disclose or suggest every element of the claims.

For example, Oz fails to teach or suggest a supporting structure releasably coupled to the catheter, the supporting structure being adapted for deployment at a tissue location on or adjacent the annulus. Oz discloses using a structure such as a grasper to hold the valve leaflets together. However, Oz makes no mention of deploying a structure on or adjacent the annulus itself nor does Oz have any suggestion or motivation for deploying a structure on or adjacent the annulus. Indeed, at column 2, lines 4-14, Oz states:

[R]ecent studies performed by the inventors (Umana et al., Surg Forum 1997) have revealed that posterior ring annuloplasty causes changes in ventricular geometry that lead to paradoxical movement of the normal papillary muscles, further deteriorating ventricular performance. In contrast, the "bow-tie" repair in which the anterior and posterior leaflets of the mitral valve are fixed in opposition appears to enhance annular contractility while preserving ventricular architecture. This has resulted in improved postoperative ventricular function almost uniformly.

Oz distinguishes annuloplasty from "bow-tie" repair in which a structure is deployed on the valve leaflets, not on the annulus. Oz teaches that annuloplasty (deployment of a structure on the annulus) leads to "deteriorating ventricular performance." Oz therefore teaches away from deploying a structure on or adjacent the annulus.

In view of the foregoing, applicant respectfully submits that the rejection of claim 1 under 35 U.S.C. §102(e) should be withdrawn. Claims 8-10, 12, and 14-18 all depend from claim 1 and are patentable over the prior art for at least those reasons articulated with respect to claim 1, as well as on their own merit.

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Rejection of Claim 11 under 35 U.S.C. 8103

Claims 11 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Oz in view of U.S. Patent Number 5,450,860 to O'Connor. However, as discussed above, Oz fails to teach or suggest all of the limitations of independent claim 1 from which claim 11 depends. For example, Oz fails to teach or suggest a supporting structure releasably coupled to the catheter, the supporting structure being adapted for deployment at a tissue location on or adjacent the annulus. O'Connor fails to provide the missing teaching. Claim 11 is patentable over Oz and O'Connor based on its dependency on claim 1 as well as on its own merit. Applicant requests that the examiner withdraw the rejection of claim 11.

Rejection of Claims 43, 51 and 53-61 under 35 U.S.C. §103

Claims 43, 51 and 53-61 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Number 5,593,424 to Northrup in view of Oz. However, there is no motivation or suggestion to combine the disclosure of Oz with the disclosure of Northrup. Moreover, even when Northrup and Oz are combined, the subject matter of claim 43 is neither taught nor suggested.

Claim 43 recites:

43. A method of modifying a valve in a patient's heart to reduce regurgitation, the valve having an annulus, the method comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter carrying a plurality of anchors;

placing the anchors on or adjacent the annulus; coupling a filament to the anchors; and tightening the filament so as to modify the annulus to reduce regurgitation in the valve.

The examiner acknowledged in the office action that Northrup does not teach a method of delivering the anchors. The examiner filled in the gap with Oz and argued that Oz teaches that it is known to deliver a device to the annulus of the heart valve via a delivery eatheter. Applicant disagrees with the examiner regarding the teachings of Oz. Oz relates to grasper with jaws that

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grasps the leaflets of a heart valve. Oz makes no mention of delivering a device to the annulus of a heart valve. Indeed, Oz teaches away from delivering a device to the annulus. As discussed above, Oz teaches that annuloplasty (deployment of a structure on the annulus) leads to "deteriorating ventricular performance." Thus, there would have been no suggestion or motivation for a person of ordinary skill to look to Oz for a method of delivering anchors to the annulus. Applicant respectfully submits that the examiner should provide some basis as to why Oz would be combined with Northrup in view of the fact that Oz teaches away from deployment of a structure on the valve annulus.

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Moreover, the combination of Oz with Northrup does not result in the method of claim

43. The device disclosed in Oz is structurally unsuited for placing anchors on the annulus.

Rather, the Oz device is a grasper that grabs and coapts the leaflets. The examiner has provided no basis as to how such a grasper could be used in a method that involves the step of placing anchors on the annulus, as recited in claim 43. Applicant requests that the examiner explain how the grasping device in Oz could be used to place anchors on the annulus as recited in claim 43. Absent such an explanation, the examiner should withdraw the rejection of claim 43.

In view of the foregoing, applicant respectfully submits that the rejection of claim 43 should be withdrawn. Claims 51 and 53-61 all depend from claim 43 and are patentable over the prior art for at least those reasons articulated with respect to claim 43, as well as on their own merit.

Claim 52

Applicant notes that the examiner did not reject claim 52. As discussed above, none of the cited art discloses or suggests the subject matter of independent claim 43 from which claim 52 depends. Nor does the cited art disclose or suggest the subject matter of claim 52 ("The method of claim 43, wherein the anchors on or near the annulus comprise staples.") In view of the foregoing, claim 52 should be in condition for allowance. Should the examiner reject claim 52 in a subsequent office action, applicant respectfully submits that such office action should be non-final in view of the fact that the examiner did not provide any reason for rejection of claim 52 in the instant office action.

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Conclusion

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

In view of the amendments and remarks herein, Applicants believe that all claims are in condition for allowance and ask that these pending claims be allowed. The foregoing comments made with respect to the positions taken by the Examiner are not to be construed as acquiescence with other positions of the Examiner that have not been explicitly contested. Accordingly, the arguments for patentability of a claim should not be construed as implying that there are not other valid reasons for patentability of that claim or other claims.

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Respectfully submitted,

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